

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

DePuy Mitek, Inc.)	
a Massachusetts Corporation)	
)	
Plaintiff,)	
)	
v.)	Civil No. 04-12457 PBS
)	
Arthrex, Inc.)	
a Delaware Corporation and)	
)	
Pearsalls Ltd.)	
a Private Limited Company)	
of the United Kingdom)	
Defendants.		

**DePuy Mitek's Memorandum in Support of Its Motion for Summary Judgment of
Infringement & Opposing Arthrex's Motion for Summary Judgment of Noninfringement**

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I. Introduction and Overview

Plaintiff, DePuy Mitek, Inc. (“Mitek”) submits this memorandum pursuant to the Court’s January 31, 2007 Order (“Order”) (Ex.1) permitting the parties a single brief to address Mitek’s motion for summary judgment of infringement and Defendants’, Arthrex, Inc.’s and Pearsalls Ltd.’s¹, motion for summary judgment of noninfringement, each of which had been previously submitted.

Although the parties’ briefs touch on other issues, the main disagreement between the parties is whether the silicone coating on the surface of Arthrex’s accused FiberWire sutures removes them from the scope of Mitek’s patent claims because the claims use “consisting essentially of” language. This language excludes from the claims sutures having unlisted components which materially affect the basic and novel characteristics of the invention. Although the arguments and evidence on this point will be discussed in more detail below, Mitek believes it might help the Court to address one point at the outset. Specifically, the Court might wonder how Mitek can contend that summary judgment of infringement can be granted as a matter of law, while contending that genuine issues of material fact preclude granting Arthrex’s motion for summary judgment of noninfringement. This is why.

Mitek contends that the question of whether the surface coating on FiberWire has a material effect on the basic and novel characteristics of the invention can be answered as a matter of law because the 446 Patent expressly contemplates that the inventive sutures may have such surface coatings. The patent states, “[i]f desired, the *surface* of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating to further improve the

¹ Arthrex, Inc. and Pearsalls Ltd. are jointly represented. Except where noted, “Arthrex” refers collectively to Arthrex, Inc. and Pearsalls Ltd. Mitek’s motion addresses Arthrex, Inc.’s infringement. Pearsalls Ltd. is also liable for indirect infringement under 35 U.S.C. §§271(b) and (c), but Mitek does not raise those issues here. This memorandum is supported by its previously submitted Statements of Facts Exhibits attached thereto (Exs. 3-5).

handleability and knot tiedown performance of the braid” (Ex. 2 at 6:5-8). The patent, therefore, “directly speaks to and conclusively answers the question of what constitutes a material effect, [so] the issue [of what is a material effect] may be resolved as a question of law” (Ex. 1 at 14). Thus, the Court may rule, as a matter of law, that FiberWire’s surface coating does not materially affect the suture.

Arthrex, on the other hand, disagrees that the issue of materiality can be decided as a matter of law in this case. According to Arthrex, one must look to various pieces of evidence purporting to compare the differences between FiberWire suture with and without coating. But as soon as the test devolves into a question of what effect the silicone surface coating has on the handleability or other properties of FiberWire, there are genuine issues of material fact that preclude a dispositive ruling.

In short, if the Court agrees that, because of the disclosure in the 446 Patent, it can rule as a matter of law that FiberWire’s surface coating does not have a material effect, then summary judgment of infringement can be granted. But if the Court does not agree that it can so rule as a matter of law, then there are genuine issues of material effect precluding summary judgment.

Mitek addresses its motion for summary judgment of infringement in Section II and addresses Arthrex’s motion for summary judgment of noninfringement in Section III.

II. Mitek’s Motion for Summary Judgment of Infringement Should Be Granted

There is no genuine dispute that the accused FiberWire PET/PE braided sutures literally possess each and every element recited in Claims 1, 2, 8, 9 and 12 of Mitek’s 446 Patent (Ex. 6 at ¶¶33-50).

Arthrex devotes its major attention to a technical non-infringement argument that it somehow avoids infringement by applying a silicone coating to its PET/PE suture braid. But accepting this argument requires the Court to decide that one can *materially affect* the basic and

novel properties of the claimed suture *by doing exactly what the patent expressly teaches*, namely, coating the surface of the suture braid “to further improve the handleability and knot tiedown performance of the braid” (Ex. 2 at 6:5-12). As explained below in Section II.C, because the 446 Patent expressly contemplates such surface coatings, the Court can decide, as a matter of law, that the surface coating on FiberWire does not materially affect its basic and novel characteristics.

Arthrex’s only other remaining noninfringement argument is based on an arcane legal doctrine that the Federal Circuit has never upheld. As explained below in Section II.D, that argument, that the reverse doctrine of equivalents saves FiberWire from infringement even though the Court construed “PE” to literally encompass the ultra high molecular weight PE used by Arthrex, is without merit.

A. The Claimed Invention Was Aimed at Improving Multifilament Suture Properties By Mechanically Blending Certain Yarns

The problem addressed by the 446 Patent was how to improve multifilament suture properties (Ex. 2 at 2:29-31). The prior art had focused on improving multifilament suture properties by using coatings, melting, and manufacturing processes (*id.* 1:33-2:13). According to the 446 Patent, certain coatings and processes were not, in and of themselves, sufficient to improve multifilament suture properties because, *inter alia*, they significantly bonded the individual fibers together and inhibited fiber movement, causing the multifilament suture to behave like a monofilament (*id.* at 1:12-25). The 446 Patent inventors found a different way to improve suture properties. They discovered that improved sutures could be made by “mechanically blending” multifilament yarns of different materials. By forming a *heterogeneous* braid having, for example, multifilament polyethylene (“PE”) yarns braided in direct intertwining contact with multifilament polyethylene terephthalate (“PET”) yarns (*id.* at 8:63-

9:8), the 446 Patent inventors discovered sutures having improved properties, “attributable to the specific properties of the dissimilar fiber-forming materials” (*id.* at 2:40-66), compared to prior art *homogeneous* multifilament sutures (*id.* at 2:29-31; 2:62-66).

Although the 446 Patent recognized drawbacks of certain coatings used in the prior art -- for example, those that significantly bonded the fibers in the suture together and inhibited fiber movement -- the patent does not exclude all coatings from the invention. Indeed, the 446 Patent explicitly teaches:

If desired, the *surface* of the heterogeneous multifilament braid can be coated with a bioabsorbable or nonabsorbable coating *to further improve* the handleability and knot tiedown performance of the braid. For example, the braid can be immersed in a solution of a desired coating polymer in an organic solvent, and then dried to remove the solvent. Most preferably, the coating does not cause the fibers or yarns to adhere to one another increasing stiffness. However, if the surface of the heterogeneous braid is engineered to possess a significant fraction of the lubricious yarn system, the conventional coating may be eliminated saving expense as well as avoiding the associated braid stiffening.

If the *surface* of the braid is coated, then the coating composition may desirably contain bioactive materials such as antibiotics and growth factors.

(*id.* at 6:5-21, emphasis added).

Thus, it cannot be disputed that, while the 446 Patent recognized drawbacks of certain specific coatings, the patent contemplates a suture having a *surface* coating, which “further improves handleability and knot tiedown performance,” as being precisely within the scope of the invention.

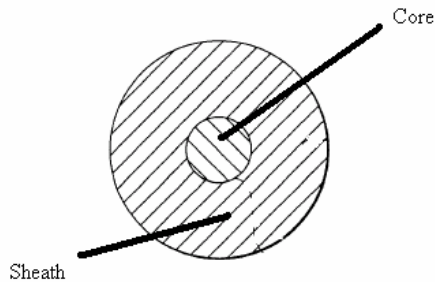
B. Arthrex’s FiberWire Products

As illustrated in the following diagrams, FiberWire² has a polyethylene core (except for one size of FiberWire) and a sheath or cover formed by braiding multifilament PE and PET yarns

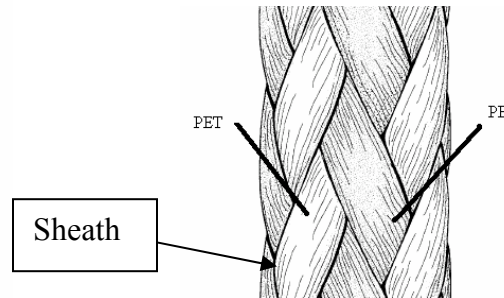
² “FiberWire” refers to all of Arthrex’s FiberWire and TigerWire products. Although Arthrex had previously argued that Tiger Wire does not infringe because it includes some nylon filaments, it has now agreed that TigerWire’s nylon does not materially affect the novel and

in direct intertwining contact (Ex. 8 at 43:15-19; Ex. 9; Ex. 10 at 362:9-14), just as recited in the 446 Patent claims (Ex. 2 at 8:63-9:9).

Diagrammatical Cross-Section of FiberWire



Diagrammatical Top View Of FiberWire



FiberWire also has a surface coating, just as taught in the 446 Patent (*id.* at 6:5-13). The surface coating is silicone, trade named NuSil Med2174 (Ex. 6 at ¶47).

Undisputed evidence shows that the silicone coating on FiberWire is a surface coating that does not significantly permeate the braid yarns (and thereby cause them to adhere to one another). For example, the amount of the coating is so small that Pearsalls, the manufacturer of FiberWire, considers it to be not capable of measurement (*id.*).³ FiberWire's FDA-approved Instructions for Use describe FiberWire's coating as a mere "lubricant" (Ex. 9). Mitek's expert, Dr. Brookstein, also confirmed that FiberWire's coating is just a surface coating (Ex. 6 at ¶¶47, 48, 62-64) based on, *inter alia*, his magnified photographs (*id.* at Exs. 20-22) and first-hand observation of FiberWire being manufacturing (*id.* at ¶47). The coating is applied by passing the

basic characteristics (Ex. 7). Therefore, TigerWire infringes Mitek's 446 Patent for the same reasons that FiberWire infringes.

³ Arthrex alleges that FiberWire has a relatively large amount of coating based on Dr. Brookstein's measurements as compared to certain alleged disclosures of amounts of coatings. But that is not true because Arthrex's comparisons are either just wrong or irrelevant. Arthrex's Ex. 11 discloses the percent by weight of a substance in the "reaction medium" used to form a coating, not the percent by weight of suture on a coating (Arthrex Ex. 11 at 2:46-49), and Arthrex's Ex. 23 at 3:25-30; 3:62-4:1 discusses the amount of *dry powder coating* on a *monofilament* and is irrelevant. In contrast to FiberWire, some sutures have a coating that is 10% by weight (Ex. 19 at DMI0000170).

PE/PET braid quickly through a solution of coating and solvent, passing the braid through pads that wipe off excess solution, and then drying (Ex. 6 at ¶¶47; 53; 61), just as the 446 Patent specifies a surface coating may be applied (Ex. 2 at 6:9-11). Dr. Brookstein concluded that FiberWire's coating did not substantially permeate the braid because the yarn fibers are not bound together and the individual PE and PET fibers and yarns retain their morphology (Ex. 6 at ¶¶47, 48, 62-64; *id.* at Exs. 20-22). Arthrex has proffered no evidence to create a genuine issue of fact regarding the nature of the coating on FiberWire.⁴ It is indisputably a surface coating, as expressly contemplated by the 446 Patent.

C. Arthrex Cannot Escape Literal Infringement Based On the “Consisting Essentially of” Phrase

1. “Consisting Essentially Of” Only Excludes Elements Materially Affecting Basic and Novel Properties

As FiberWire literally has all of the limitations of Mitek's claims, Arthrex tries to evade infringement based on the “consisting essentially of” transitional claim language. Arthrex's arguments are legally erroneous. Because of this transitional phrase, the claims of the 446 Patent cover sutures that include the listed ingredients as well as unlisted ingredients that do not *materially affect* the basic and novel properties of the invention. *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1239 (Fed. Cir. 2003).

This Court's Order defines the basic and novel characteristics of the claimed invention as:

“(1) a surgical suture; (2) composed of two dissimilar yarns from the lists in Claim One, (3) where at least one yarn from the first set is in direct intertwining contact with the yarn from the second set, (4) so as to improve pliability and

⁴ Although Arthrex may try to create a fact issue about whether FiberWire's coating is a “surface coating” it cannot. Arthrex's experts did not witness FiberWire being manufactured. Further, Arthrex submits no pictures of FiberWire. Thus, to the extent Arthrex submits a bare conclusory expert report from Dr. Mukherjee regarding the issue, that conclusory “evidence” is insufficient to create a fact issue.

handleability without significantly sacrificing the physical properties of the constituent elements of the suture”

(Ex. 1 at 18-19).

2. As a Matter of Law, FiberWire’s Surface Coating Does Not Materially Affect Basic and Novel Properties

As the Court recognized in its Order, in attempting to improve suture properties, the prior art had overlooked the importance of fiber-fiber friction and its impact on fiber mobility and braid pliability (*id.* at 17). Prior art methods frequently attempted to improve suture properties by using coatings which significantly restricted the movement of adjacent filaments of the braid (*id.*). As explained above, the benefits of the invention claimed in the 446 Patent are realized by mechanically blending dissimilar yarns in direct intertwining contact (Ex. 2 at 2:32-37; 2:49-66; 3:40-51; 8:50-61). But the 446 Patent also teaches that, once those advantageous suture properties are realized by the formation of the heterogeneous braid, they can be *further enhanced* by applying a surface coating to the suture (*id.* at 6:5-21). The 446 Patent therefore “directly speaks to and conclusively answers the question of what constitutes a material effect,” as the Court noted in its Order a patent can do (Ex. 1 at 14). The Patent directly states that surface coatings which further enhance properties are contemplated by the invention. Since it is undisputed that FiberWire’s coating is a surface coating (it does not substantially penetrate the braid interstices, does not materially affect “fiber mobility,” “movement of adjacent filaments,” the dissimilar yarn fibers, direct intertwining contact, or the resulting suture properties) (Ex. 6 at ¶¶44; 47; 53; 62-64)), this Court can and should rule, as a matter of law, that FiberWire’s silicone coating does not materially affect the basic and novel properties of the suture.

Trying to avoid summary judgment, Arthrex incorrectly tries to spin a single sentence from column 6, lines 13-17 of the 446 Patent as “criticizing” the use of coatings and stating that it is “best to ‘avoid’” coatings. But the 446 Patent says neither thing. Rather, it merely states

that, in certain limited circumstances where the amount of lubricous yarn in the suture is significant enough, a “conventional coating *may* be eliminated” saving expense and avoiding potential stiffening (Ex. 2 at 6:16-17) (emphasis added). “May” does not equal “criticize” or “best.” Consistent with the remainder of the 446 Patent disclosure, the use of the term “may” indicates that the coating is optional or immaterial.⁵

Arthrex tries to suggest that the Court adopted Arthrex’s construction, and that Mitek’s counsel admitted that there would be issues of fact precluding summary judgment of infringement if Mitek’s construction were not adopted. But the Court did not adopt Arthrex’s construction in total, and therefore based on the Court’s construction and its statement of the law of materiality, the Court can decide Mitek’s motion as a matter of law (Ex. 1 at 14, citing *AK Steel*, 344 F.3d at 1240).⁶

Arthrex cites *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 239 F. 3d 1239 (Fed. Cir. 2001), for the proposition that materials disclosed in the patent and not recited in the claims can materially alter the basic and novel properties of the invention. The case, however, does not stand for that broad proposition. The patent asserted in *AFG Indus.* disclosed that the unlisted ingredient, an interlayer, did not have a material affect if it improved adhesion but did not

⁵ Arthrex incorrectly contends that the 446 Patent criticizes FiberWire’s coating because it is supposedly a “thermoset” and the 446 Patent supposedly criticizes all thermoset coatings. But Arthrex’s cited “evidence” does not even mention “thermoset” (Arthrex Ex. 24), and there is no evidence defining a “thermoset.” Further, the 446 Patent does not “criticize” all thermoset coatings. Rather, it refers to a “particular” PTFE thermoset coating that has a “tendency to flake off during use” (Ex. 2 at 1:48-53). FiberWire’s coating is indisputably not PTFE.

⁶ See also *PPG Indus. v. Guardian Indus. Corp.*, 156 F. 3d 1351, 1356-57 (Fed. Cir. 1998) (considering patent specification and prosecution history in considering whether effects are material); *Ex parte Boukidis*, 154 U.S.P.Q. 444, 444 (B.P.A.I. 1966) (finding that the expression “consisting essentially of” does not exclude ingredients from the scope of the claims when the specification clearly indicates that other ingredients may be present); *Bayer AG v. Sony Elecs., Inc.*, 229 F. Supp. 2d 332, 343-344 (D. Del. 2002) (considered intrinsic record to determine whether it defined what was per se a material effect); *BASF Corp. v. Eastman Chem. Co.*, No. 95-746-RRM, 1998 U.S. Dist. LEXIS 23054, *28-30 (D. Del. Mar. 24, 1998) (Ex. 18).

substantially affect the optical properties. *Id.* at 1242. The Federal Circuit specifically adopted this standard as the materiality standard. *Id.* at 1252. Because the materiality standard matched the disclosure, if the unlisted ingredient, the interlayer, satisfied the materiality standard, then it also was disclosed as being part of the invention. Thus, *AFG Indus.* actually supports Mitek's position that the Court should adopt the materiality standard defined in the 446 Patent.

Arthrex now alleges that the 446 Patent's prosecution history indicates that the "consisting essentially of" language excludes all coatings. An examination of the prosecution history (Ex. 19) shows that the addition of "consisting essentially of" to the claims had nothing to do with coatings. As Mitek explained in its *Markman* briefing, the "consisting essentially of" language was added to the claims to exclude certain bioabsorbable yarns. Ironically, in response, Arthrex argued that "The Reasons for Adding 'Consisting Essentially of' to the Claims [sic] *Has No Impact On Whether An Unrecited Ingredient Materially Affects the Novel and Basic Characteristics*" (D.I. 55 at 5) (emphasis added), and the Court addressed the reasons for adding the "consisting essentially of" language separate from defining the novel and basic characteristics (Ex. 1 at 16). Arthrex's position now, that the prosecution history somehow shows that the "consisting essentially of" language excludes coatings, is inconsistent with its prior position.

In summary, even accepting as true Arthrex's factual allegations that FiberWire's surface coating improves knot-tying and handleability, summary judgment of infringement is warranted as a matter of law because the 446 Patent explicitly contemplates such coatings.

3. Arthrex's Tipping Allegations Are Legally Erroneous

Although it is not clear if Arthrex is maintaining this argument, it had previously made an additional "consisting essentially of" argument, alleging that FiberWire does not infringe because about one inch of both ends of the about 38 or 18 inch long FiberWire sutures (Ex. 13 at

13-1) are “tipped” by adding an adhesive to the ends to prevent fraying and to allegedly provide other characteristics (D.I. 61 at 8). Arthrex’s argument is legally erroneous for two reasons. First, as long as 36 or 16 inches of FiberWire infringes, it is irrelevant as a matter of law whether FiberWire’s ends infringe.⁷ As the Federal Circuit has explained, “a pencil structurally infringing a patent claim would not become noninfringing when incorporated into a complex machine that limits or controls what the pencil can write.” *A.B. Dick Co.*, 713 F.2d at 703. Second, because “tipping” suture *ends* is a standard procedure in making sutures and wholly irrelevant to the claimed invention, infringement is not precluded by tipping.⁸

D. FiberWire Literally Has “PE” As Construed By the Court

1. “PE” Was Construed to Encompass Arthrex’s UHMWPE

The Court has construed the claim term “PE” to mean “all polymers formed from a repeating ethylene monomer, including UHMWPE” (ultra high molecular weight polyethylene) (Ex. 1 at 12). FiberWire has this limitation because it includes a polymer formed from a repeating ethylene monomer, namely, UHMWPE (Ex.11 at ¶6; Ex. 8 at 43:15-19). Nonetheless, Arthrex erroneously argues that the “PE” claim limitation is not met because of the “reverse doctrine of equivalents.”

⁷ *Suntiger, Inc. v. Scientific Research Funding Group*, 189 F.3d 1327, 1336 (Fed. Cir. 1999) (holding that the “district court's error lies in the fact that we have never required that a claim read on the entirety of an accused device in order to infringe”); *A.B. Dick Co. v. Burroughs Corp.*, 713 F.2d 700, 703 (Fed. Cir. 1983) (stating that inclusion of an infringing device into a larger device does not escape infringement).

⁸ *Conoco, Inc. v. Energy & Envtl. Int'l, L.C.*, 460 F.3d 1349, 1360-61 (Fed. Cir. 2006) (holding that additional element unrelated to the claimed invention did not preclude infringement even where claim had the more restrictive generally closed “consisting of” transitional phrase); *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331-1332 (Fed. Cir. 2004) (reversing summary judgment of noninfringement because addition of an element that was unrelated to the claimed invention did not preclude infringement of claim for a kit “consisting of” certain elements).

2. Undisputed Facts Establish that Arthrex Does Not Avoid Infringement Under the “Reverse Doctrine of Equivalents”

Under the reverse doctrine of equivalents, an accused product that falls within the literal words of a claim may not infringe if the product “is so far changed in principle from a patented article that it performs the same or a similar function in a substantially different way.” *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608-609 (1950). Arthrex cites no Federal Circuit from its twenty-five years of existence affirming a judgment based on this obscure legal doctrine.⁹

Even if the reverse doctrine of equivalents has any vitality, it is of no help to Arthrex. Arthrex’s reverse doctrine of equivalents allegations are premised on the notion that the claimed first set of yarns “contributes pliability and handleability characteristics to the braid” and the claimed “second set provides added strength,” and that FiberWire’s PE and PET allegedly operate in “exactly the opposite” way (D.I. 61 at 9). But even accepting Arthrex’s functional allegations regarding the claimed yarns as true for purposes of Mitek’s motion, (Mitek disputes them otherwise), it is undisputed that FiberWire’s yarns satisfy these functions and that the reverse doctrine of equivalents does not apply.

As to the first set of yarns, it is undisputed that FiberWire’s PE is lubricous (Ex. 10 at 239:10-13; 296:4-6; Ex. 12 at 52:24-53:1). It is also undisputed that, since FiberWire’s PE is lubricous, it improves compliance, lubricity, and fiber-to-fiber movement, and therefore contributes to handling and pliability properties (Ex. 6 at ¶¶38, 40, 41, 45), just as the 446 Patent teaches (Ex. 2 at 4:11-14). Therefore, based on the undisputed evidence, FiberWire’s PE satisfies Arthrex’s alleged function of “contribut[ing] pliability and handleability.”

⁹ In the only case cited by Arthrex in its original opposition pertaining to the doctrine, the Federal Circuit remarked that: “[n]ot once has this court affirmed a decision finding noninfringement based on the reverse doctrine of equivalents.” *Tate Access Floors, Inc. v. Interface Architectural Res., Inc.*, 279 F.3d 1357, 1368 (Fed. Cir. 2002) (emphasis added).

Further, it is undisputed that FiberWire's PET improves FiberWire's knot holding strength (*id.* at ¶38). Mr. Grafton, Arthrex's former vice-president and designer of FiberWire, admitted that PET makes FiberWire stronger because, without it, a PE-only suture was too weak to hold a knot (Ex. 12 at 51:22-52:15; 53:20-54:5). Thus, based on undisputed evidence, FiberWire's PET satisfies Arthrex's alleged function of "provid[ing] strength." Even accepting Arthrex's alleged functions of the claimed yarns as true, the undisputed facts still show that FiberWire operates in accordance with, not opposite to, the teachings of the 446 Patent. The reverse doctrine of equivalents simply does not apply.¹⁰

For all of the reasons above, summary judgment of infringement should be granted. The Court may determine, as a matter of law, that the surface coating Arthrex applies to FiberWire suture – according to express teachings of the 446 patent – does not materially affect the basic and novel characteristics of the suture. And there are no genuine issues of material fact precluding a conclusion that FiberWire meets every other element of the 446 Patent claims.

III. Arthrex's Motion for Summary Judgment of Noninfringement Should Be Denied

Arthrex's motion for summary judgment of noninfringement is predicated on the single allegation that FiberWire's coating materially affects the 446 Patent claims' novel and basic characteristics. If the Court resolves this issue as a matter of law based on the 446 Patent's materiality definition (Section II), then it can simply deny Arthrex's motion without considering the issue further. But if Arthrex's motion must be considered, it should be denied because Mitek has satisfied its summary judgment burden of producing evidence from which a reasonable jury

¹⁰ Arthrex may try to create a factual issue by asserting that FiberWire's PE contributes to strength and PET contributes to handleability. But those allegations are irrelevant because even if they are true, there is no evidence that FiberWire's PE does not also contribute to handleability and that FiberWire's PET does not also contribute to handleability. Thus, the mere fact that Arthrex alleges that the yarns perform other functions does not create a factual dispute.

could and should find for it on the infringement issue. At most, Arthrex's submission of other evidence or arguments about the meaning of Mitek's evidence raises factual and credibility disputes that render summary judgment in Arthrex's favor improper.

A. Granting Arthrex's Motion as a Matter of Law Based on the 446 Patent Would Be Legal Error

Arthrex contends that the 446 Patent defines all coatings as a matter of law as materially affecting the novel and basic characteristics. But Arthrex is wrong for the reasons explained above. The 446 Patent expressly contemplates the use of surface coatings which can further improve the properties of the sutures (Ex. 2 at 6:5-8). If the Court does not agree with Mitek that it may decide the materiality issue as a matter of law, then it is a question of fact – and the question is rife with factual disputes.

B. Arthrex Ignores the “Materiality” Aspect of the Test

In trying to cast all coatings as disallowed by the 446 Patent claims, Arthrex chooses to ignore the fact that the “consisting essentially of” language only excludes elements which *materially* alter the basic and novel characteristics of the suture. Thus, even if it is accepted that the coating on FiberWire affects certain handleability properties of the suture (and Mitek does not agree that it does), not just any effect is a *material* effect.

C. Arthrex Relies on Evidence of Sutures and Coatings Unrelated to FiberWire

Arthrex discusses at length evidence that has nothing to do with FiberWire and its particular coating. FiberWire has a specific silicone coating, applied in a specific amount, in a specific way, to a specific product (Ex. 6 at ¶¶47, 62-64). But Arthrex cites “evidence” about other coatings, coatings that are applied in another unidentified manner, and sutures not having

the novel and basic characteristics, much less the claimed yarns braided as claimed.¹¹

Moreover, the premise of its argument – that all coatings enhance handleability – is just not true because certain coatings detract from handleability because they “adhere[] fibers together” or caused “increased stiffness” (Ex. 2 at 1:18-22; 64-67; *see also* Arthrex Ex. 10 at 1:44-49 describing coating as stiffening).

D. Mitek Has Submitted a Wealth of Evidence From Which a Reasonable Jury Could Find for It on the Materiality Issue

Mitek has produced substantial evidence from which a reasonable juror could conclude that FiberWire does not have a material effect on the novel and basic characteristics of the invention, and this evidence must be viewed in the light most favorable to Mitek, the non-movant.

1. The Patent Disclosure Itself Raises Genuine Issues of Material Fact

If the materiality issue is one of fact, rather than law, then the explicit disclosure in the 446 Patent that surface coatings may be used to further improve suture properties is probative of what one skilled in the art would consider to be material. Mitek submitted expert testimony from Dr. Brookstein that the 446 Patent defines surface coatings, such as FiberWire’s, as immaterial

¹¹ Arthrex’s evidence references a “polyvinyl ester” coating (Arthrex Ex. 8 at 2:9-21; 2:48; Arthrex Ex. 9 at 2:6-21; 2:46); a coating comprising a “copolymer of a predominant amount of ϵ -caprolactone and the balance of glycolide and glycolic acid” (Arthrex Ex. 10 at 1:62-2:3); coatings comprising “poly(oxypropylene) glycols” (Arthrex Ex. 11 at 2:4-14); a Panocryl suture made of a copolymer of glycolide, an Orthocord suture having “NVC” coating (Arthrex Exs. 14-19); unidentified coatings and sutures not covered by the 446 Patents (Arthrex Ex. 7); unidentified coatings effects on unidentified “synthetic” sutures (Arthrex Ex. 20 at 525); and adding certain silicones to a PV Ester to form a composite coating, not a silicone coating, as Arthrex alleges (Arthrex Exs. 8 & 9 at 3:55-61). Arthrex’s other general citations are not about FiberWire’s coatings and materiality (Arthrex Exs. 12-16).

(Ex. 6 at ¶¶50-55).¹² Arthrex's expert did not opine on this issue. The patent disclosure and Dr. Brookstein's testimony on this point, at the very least, create genuine issues of material fact.

2. Dr. Burks' Testimony Raises Genuine Issues Of Material Fact

Dr. Burks, one of Arthrex's experts, admitted that, whatever effects FiberWire's coating has, they are immaterial to the person who matters -- a surgeon.¹³ Therefore, his testimony alone precludes granting Arthrex's motion.

Dr. Burks is an experienced orthopedic surgeon who has been performing surgery since about 1978 (Ex. 15 at 11:24-17:6). He conducted blind knot tie down/handleability tests of uncoated and coated FiberWire for Arthrex and at his deposition (*id.* at 70:7-72:23; 91:20-99:5).¹⁴ After examining the samples, Dr. Burks twice admitted that the differences between the coated and uncoated samples were "subtle;" that the coated and uncoated sutures were "pretty close;" and that he "could not clearly feel a difference" between the two sutures (*id.* at 87:7-13; 88:1-3; 88:9-12; 96:18-19; 98:18-21). As Dr. Burks admitted:

- Q. How would you qualify the difference that you just observed, based on your test?
A. When you say "qualify" are you asking for like an amount?

¹² Over exaggerating a snippet of Dr. Brookstein's deposition testimony, Arthrex incorrectly asserts that Dr. Brookstein had a "magic and miracles" test. Dr. Brookstein had a materiality test based on the 446 Patent which he applied to FiberWire's coating, not a so-called "magic and miracles" test (Ex. 6 at ¶¶43-64). Arthrex's sound-bite argument ignores the substance of Dr. Brookstein's testimony and his explanation in his Report that FiberWire's coating does not have a material affect because FiberWire's coating is not melted into the braid, does not substantially permeate the braid, and is not manufactured in such a way so as to "transform the braided FiberWire materials into another structure or cause it to lose its characteristics that are attributable to the dissimilar yarns being braided" (*id.* at ¶47, 61-64). Mitek does not have the brief space to address Arthrex's potshots at Dr. Brookstein's qualifications, but suffice it to say that Dr. Brookstein is qualified as an expert (*see id.* at ¶¶1-12).

¹³ At the summary judgment hearing, Arthrex's counsel argued that the materiality of FiberWire's coating should be judged through the eyes of the market or customers such as Dr. Burks (Ex. 14 at 59:19-60:1).

¹⁴ Although not relevant here, Mitek disputes whether the "coated" and "uncoated" suture examples tested by Dr. Burks were fair comparisons because the tested sutures had other manufacturing differences which enhanced any property differences between the sutures.

Q. How would you characterize the difference between the sutures?

A. *Well the difference is, I think, subtle and there's no doubt in my mind that I could line up, you know, a hundred sutures and have error where I would say, you know, I think this one is one way or the other and make a mistake. So there's certainly not enough difference to clearly say that I know every time exactly how that feels.*

(*id.* at 97:15-98:3) (emphasis added). Although Arthrex tries to make much of the fact that he supposedly performed his blind tests correctly, that is really irrelevant. What is relevant is how he quantified the differences, namely as “subtle” or immaterial.

Dr. Burks further admitted that the coating was immaterial because he was not even sure that he could tell the difference in the setting that matters, namely, the surgical environment where surgeons handle FiberWire with gloves. As Dr. Burks explained, he performed his analysis with and without gloves, and he admitted that he may not have been able to determine any difference between the tested sutures if he had not taken his gloves off (*id.* at 51:12-14; 73:9-14; *see also* 96:24-97:5). As Dr. Burks admitted, not having gloves “makes a difference” in distinguishing between coated and uncoated FiberWire (*id.* at 72:4-23).

At the *Markman* and summary judgment hearing, the Court correctly pointed out that Dr. Burks’ testimony showed that FiberWire’s coating’s effects were “subtle” or immaterial (Ex. 1 at 55:1-56:6; 58:12-13). Grasping for a response, Arthrex alleged that Mitek’s arguments were insufficient because Mitek was allegedly merely criticizing Arthrex’s experts (*id.* at 60:2-6). But the Court correctly recognized that this argument was dubious because Mitek was *affirmatively relying* on Dr. Burks’s testimony as affirmative evidence, *not criticizing* it (*id.* at 60:7-9).

Arthrex has subsequently alleged that Dr. Burks’ “subtle” and “pretty close” testimony was supposedly only true regarding the sutures when they were dry, and that comparing wet sutures was all that matters (Ex. 16 at 8). The problem for Arthrex is that this spin is contrary to the record. Dr. Burks was asked about his “tactile feel” test in total, which encompassed both

wet and dry sutures (Ex. 17 at ¶11). He admitted that the coated and uncoated sutures were “pretty close” (*i.e.* the differences were immaterial (Ex. 15 at 87:14-88:3)). Further, Dr. Burks was specifically asked about wet sutures, and he admitted that, when analyzing knot tie-down of all the sutures, it was not fair to say that there was always a difference (*id.* at 84:25-86:1). Despite numerous open-ended questions about his comparisons, he repeatedly testified that the differences were “subtle” or “pretty close,” and he never raised any wet-dry distinction (*id.* at 87:7-13). Also, when he conducted his blind analysis at the deposition, he was offered the use of water (*id.* at 92:13-16), but he chose not to use it. Surely, he wanted to get it right at the deposition, so if water really could make that big of a difference, he would have used it to distinguish between the sutures.

Dr. Burks’ un rebutted testimony -- that not using surgical gloves makes a difference and that he could not opine that there were differences between coated and uncoated FiberWire if he just used gloves – puts to bed Arthrex’s contention that there is any material difference between coated and uncoated FiberWire (*id.* at 73:9-14; 96:24-97:14). At the very least, Dr. Burks’s testimony – which must be viewed in the light most favorable to Mitek on Arthrex’s motion – creates genuine issues of material fact which preclude granting Arthrex’s motion.¹⁵

¹⁵ Dr. Burks’ spoliation of evidence creates further genuine issues of material fact. Dr. Burks did not retain an email to Arthrex’s counsel after he conducted the so-called blind tests describing “what [he] thought,” (*id.* at 74:24-77:1). He also disposed of the spools allegedly containing the coated and uncoated samples he tested (*id.* at 64:7-18), so Mitek was not afforded the opportunity to confirm whether the spools were labeled correctly and contained the correct samples. Under the spoliation doctrine, a jury may infer from a party’s “obliteration of a document relevant to a litigated issue that the contents of the document were unfavorable to that party.” *Testa v. Wal-Mart Stores*, 144 F.3d 173, 177 (1st Cir. 1998). To impose this negative inference sanction, Mitek need only proffer evidence sufficient to permit the jury to find that the persons involved with the spoliation knew of (a) the litigation or the potential for litigation; and (b) the document’s potential relevance to the litigation. *Id.* There can be no reasonable dispute that these prerequisites are satisfied. Since the trier of fact can draw a negative inference about Dr. Burks’ testing, including that the unproduced email communication and the information that

3. Fact Witness And Expert Testimony Raise Genuine Issues of Material Fact

Mitek has additional *prima facie* proof that FiberWire's coating does not affect the novel and basic characteristics of the invention claimed in the 466 Patent. As Arthrex's witnesses admit, FiberWire's PE and PET yarns are in direct intertwining contact even though the suture is coated (Ex. 8 at 100:20-101:4; Ex. 10 at 361:17-362:14). Also, as shown in Dr. Brookstein's photographs and in his analysis of FiberWire, the coating does not affect the individual yarns or their direct intertwining contact, and does not sacrifice the physical properties of the constituent elements of the suture (Ex. 6 at ¶¶47-49; 62-64). Even Dr. Mukherjee, Arthrex's expert, admits that FiberWire's coating does not prevent FiberWire's PET and PE fibers from contributing to FiberWire's properties (Ex. 10 at 562:20-25). Thus, regardless of FiberWire's coating, the pliability and handleability that results from the selection of the yarns and from braiding them in direct intertwining contact is not affected by coating, and the constituent elements are not sacrificed (Ex. 6 at ¶47).

4. Dr. Brookstein's Unrebutted Testimony Raises Genuine Issues of Material Fact

As Dr. Brookstein explained, the story of FiberWire's development establishes that it was the mechanical blending of PE and PET, by braiding PE and PET yarns, which yielded a suture with greatly enhanced properties (Ex. 2 at 2:62-66). The effect of the silicone coating on FiberWire's properties was minimal in comparison.

Before Arthrex developed FiberWire, Arthrex sold two braided polyester (PET) sutures (Ex. 12 at 15:8-15; 22:23-25; 36:17-18). These sutures had handling problems because, as Arthrex's Mr. Grafton admits, the first polyester (PET) suture was not "compliant," and the

would have been gleaned from analysis of the samples would have been adverse to Arthrex's contentions, there exist additional, genuine issues of material fact.

second polyester (PET) suture broke when being handled and, at least according to one surgeon, “suck[ed]” (*id.* at 45:8-9). In other words, both sutures were homogeneous multifilament sutures of the type upon which the 446 Patent sought to improve (Ex. 2 at 2:65).

Originally, Mr. Grafton sought to solve the problem with a *homogeneous multifilament PE suture*. But Mr. Grafton found that this suture had a different problem; it would not hold a knot (Ex. 12 at 46:1-9; 51:4-53:5). Thus, Mr. Grafton decided to form a *heterogeneous multifilament braided suture* of PE and PET (*id.* at 46:10-19; 54:6-14), which is just what the 446 Patent claims and which therefore has the novel and basic characteristics of the invention (Ex. 2 at 8:62-9:8). He found that this heterogeneous suture, which became FiberWire, overcame the disadvantages of the homogeneous sutures; it had good strength and handleability (Ex. 12 at 54:15-55:5). In fact, a surgeon recognized the dramatic improvement attributable to the claimed invention as “killer” (*id.* at 46:16-24; 54:11-14; 75:5-11). Further, Mr. Grafton admitted that he tried to optimize FiberWire’s properties by mechanically blending the PE and PET (*id.* at 68:25-70:13), just as taught in the 446 Patent (Ex. 2 at 2:58-62). Thus, Arthrex’s development of FiberWire shows that the braiding of the PE and PET yarns in direct intertwining contact with one another created a suture with substantially improved properties, just as the 446 Patent teaches (*id.* at 2:62-66).

The question then becomes: What effect, if any, does FiberWire’s coating have on this suture that already has excellent properties? As Dr. Brookstein explained, because it is just a lubricant, FiberWire’s surface coating has a minimal effect relative to the dramatically improved handleability properties attributable to the heterogeneous braid of the invention (Ex. 6 at ¶47). Thus, Arthrex’s own technical experience and Dr. Brookstein’s testimony establish that FiberWire’s coating’s effects are not material effects. Notably, Arthrex’s experts did not

consider the effects of FiberWire's coating relative to the greatly enhanced properties arising from the mechanical blending of PE and PET per the structure claimed in the 446 Patent.

5. Granting Arthrex's Motion Based on the Disputed Factual Record Would Be Legal Error

If the determination of whether the silicone surface coating on FiberWire materially affects the basic and novel properties of the suture is a question of fact, then Mitek has submitted evidence from which a reasonable jury could find for it on the materiality issue. There are genuine issues of material fact that preclude granting Arthrex's motion.

IV. Conclusion

Arthrex's FiberWire products not only literally have every element of the 446 Patent claims, but the 446 Patent expressly teaches applying a surface coating just as Arthrex has done on FiberWire. Arthrex cannot escape infringement by doing precisely what the 446 Patent teaches to be part of the invention. Because of the express disclosure of the use of optional surface coatings in the 446 Patent, the Court should rule as a matter of law that FiberWire infringes Claims 1, 2, 8, 9, and 12 of the 446 Patent.

Alternatively, if the Court does not deem the issue of materiality to be resolvable as a matter of law, then there are genuine issues of material fact precluding a determination, on summary judgment, of whether FiberWire's coating materially affects the basic and novel properties of the suture. Arthrex's motion for summary judgment of noninfringement must be denied.

Dated: April 6, 2007

DEPUY MITEK, INC.,

By its attorneys,

/s/ Erich M. Falke

Dianne B. Elderkin

Lynn A. Malinoski

Michael J. Bonella

Erich M. Falke

WOODCOCK WASHBURN LLP

Cira Centre

2929 Arch St. - 12th Floor

Philadelphia, PA 19104

(215) 568-3100

Daniel J. Gleason (BBO #194900)

Heather Repicky

Nutter McClennen & Fish LLP

World Trade Center West

155 Seaport Boulevard

Boston, MA. 02210-2604

CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

DePuy Mitek's Motion for Summary Judgment of Infringement & Opposing Arthrex's Motion for Summary Judgment of Noninfringement; and

DePuy Mitek's Memorandum in Support of Its Motion for Summary Judgment of Infringement & Opposing Arthrex's Motion for Summary Judgment of Noninfringement

were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber
Dickstein Shapiro
1825 Eye Street, NW
Washington, DC 20006
saberc@dicksteinshapiro.com

Raymond P. Ausrotas
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109
rausrotas@toddweld.com

Dated: April 6, 2007

/s/ Erich M. Falke
Erich M. Falke